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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,416	07/27/2001	Yukio Yamori	SAEGU85.001A	1599
20995	7590	12/27/2005	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			ZUCKER, PAUL A	
			ART UNIT	PAPER NUMBER
			1621	

DATE MAILED: 12/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/890,416	<b>Applicant(s)</b> YAMORI ET AL.	
	<b>Examiner</b> Paul A. Zucker	<b>Art Unit</b> 1621	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 September 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 11 and 19-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 11 and 19-29 is/are allowed.
- 6) ☒ Claim(s) 30-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Current Status***

1. This action is responsive to Applicants' amendment of 29 September 2005.
2. Receipt and entry of Applicants' amendment is acknowledged.
3. Applicant's cancellation of claims 1-10 and 12-18 is acknowledged.
4. Applicant's addition of new claims 30-36 is acknowledged.
5. The rejection under 35 USC § 103 set forth in paragraph 6 of the previous Office Action mailed 27 June 2005 is withdrawn in response to Applicants' amendment.
6. Claims 11 and 19-36 are pending.

### ***Allowable Subject Matter***

7. Claims 11 and 19-29 are allowed. The following is a statement of reasons for the indication of allowable subject matter: Applicants have persuasively argued that based on the disclosure of Mizutani one of ordinary skill in the art could not have predicted the concomitant decrease in bone density and increase in bone breaking load and strength. This unexpected result renders the instantly claimed method patentable over the teachings of Mizutani et al (Biochemical and Biophysical research Communications 1998, 253, pages 859-863), Caspar et al (WO 00/38620-A2 07-2000) and CN1127070 (07-1996), the closest prior art.

### ***New Rejections***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 30-36 are finally rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for increasing bone breaking load and strength, does not reasonably provide enablement for treating the underlying conditions which result in a decrease in bone breaking load and strength. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue."

These factors include, but are not limited to:

- a. the breadth of the claims: In the instant case the claims are extremely broad encompassing the treatment of any of menopausal or post menopausal diseases accompanied by decrease in bone weight. The Examiner also notes that postmenopausal disease encompasses virtually every disease of the elderly female;
- b. the nature of the invention: The instantly claimed invention involves the control of bone remodeling and does not extend to the treatment of the disease state

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which results in the weakening of the bone, for example hyperparathyroidism, estrogen deficiency, etc.

- c. the state of the prior art: the state of the prior art would not allow one to predict in advance, based on Applicants' disclosure which of the variety of menopausal or post menopausal diseases could be treated using resveratrol.
- e. the amount of direction provided by the inventor: The inventor provides direction only for increasing bone weight. No direction for the treatment of any underlying disease state is provided.
- f. the existence of working examples: The only working examples provided are directed to the increase in bone density. There are no examples of the treatment of any disease or evidence presented that such treatment is possible.

Based upon the analysis above, the Examiner concludes that undue experimentation is required to make and use the claimed invention.

#### ***Examiner's Comment***

- 9. Applicants' remarks reference an article by Ezawa which is not of record in the application.

#### ***Conclusion***

- 10. Claims 11 and 19-36 are pending. Claims 30-36 are finally rejected. Claims 11 and 19-29 are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A. Zucker whose telephone number is 571-272-0650. The examiner can normally be reached on Monday-Friday 5:30-2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



**PAULA A. ZUCKER, PH.D.**  
**PRIMARY EXAMINER**